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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,931	08/27/2003	Jong-Soo Woo	DE-1500	8064

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/650,931	WOO ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 November 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☒ They raise the issue of new matter (see NOTE below);

(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See *Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: *1,5,6 and 8-10*.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

November 25, 2008

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614

Continuation of 3. NOTE:
Applicants urge the proposed amendment to claim 1 is supported by the specification on the last line of page 2 to the first line on page 3 and the Abstract, as well as on page 4, lines 21 to 23. The citations are, respectively," a sustained release composition for oral administration of a drug, which, upon in vivo administration, is capable of releasing the drug at a constant rate following zero order kinetics over a period of 24 hours or more" and "sustained-release composition…does not significantly vary with the degree of gastrointestinal motility."
Accordingly, the proposed amendment to claim 1 introduces no matter and does not find clear support in the specification.
Further search and consideration would be required subsequent to the entry of such an amendment.

Zhang teaches sustained-release compositions for oral administration comprising nifedipine. See column 16, claims 22-24, where the dosage forms are an oral transmucosal patch, in addition to a lozenge/troche, a lollipop or a chewing gum. See claim 28, where nifedipine is specifically disclosed as a pharmaceutical agent encompassed in Zhang's teaching. As required by instant claim 8, non-steroidal anti-inflammatory agents and antibiotics are further encompassed in Zhang's disclosure. See column 6, lines 51-53. Zhang teaches sodium alginate, xanthan gum, hydroxypropyl methylcellulose (HPMC) and propylene glycol alginate are ingredients that may be formulated with a drug for oral administration. Zhang provides a mechanism of controlling drug release by controlling dissolution and disintegration.
Baichwal teaches a combination of a gelling agent and an inert diluent, i.e., a mixture of xanthan gum and locust bean gum, with or without a cross-linking agent and hydrophilic polymer, i.e., hydroxypropylmethylcellulose, provides a product to which the desired active medicament (nifedipine) is physically admixed. See column 8, lines 19-27. The bioavailability of nifedipine, a poorly soluble drug, is thus increased. The open language of the present claims allows for the inclusion of any number of additional active or inactive agents.
While conceding the four components of the present invention, i.e., HPMC, propylene glycol alginate, sodium alginate and xanthan gum, are included in Zhang's teaching, Applicants argue Zhang is directed to an oral transmucosal delivery system. Further, although Applicants concede Baichwal is directed to a sustained release formulation, Applicants urge the formulation of Baichwal fails to use a hydrophilic polymer and the formulation of Baichwal fails to release the drug at a constant rate following zero order kinetics for 24 hours or more.
Applicants' arguments in response to this rejection are based on the proposed amendment to claim one.
The rejection of record under 35 U.S.C.103 is maintained for the reasons of record.

Each of the three references cited on the PTO Form 1449 filed March 21, 2007 is cited on PTO Form 892 mailed March 15, 2007.